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| 10/611,442      | 06/30/2003  | C. Richard Hutchinson | 300622009100        | 4956             |

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| EXAMINER |
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ROBINSON, HOPE A

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| ART UNIT | PAPER NUMBER |
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1652

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/17/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/611,442

Applicant(s)

HUTCHINSON ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 16, 17, 21, 22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 16, 17, 21, 22 and 24 is/are rejected.
- 7) ☒ Claim(s) 25-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 4/12/07
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's response to the Office Action mailed January 29, 2007 on February 8, 2007, 2006 is acknowledged.

### ***Claim Disposition***

2. Claims 1-3, 16-17, 21-22 and 24-31 are pending and are under examination.

### ***Information Disclosure Statement***

3. The foreign document WO/00/62873, previously objected to has been reviewed. A copy of the PTO-1449 Form for the Information Disclosure Statement filed on January 6, 2004 is attached to the instant Office action.

### ***Claim Rejections - 35 USC § 112***

4. Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, is not enabled for the full scope of the claims. The specification is enabled for a cell that naturally produces or is transformed to produce the polykeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is

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sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue because the claimed invention is not commensurate in scope with the claims. The claimed method is directed to a method of producing a modified polyketide, comprising culturing a recombinant cell comprising a nucleic acid of claim 1. The claim does not set forth for example that the cell is transformed with the nucleic acid of claim 1. The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. The claimed method needs to establish that it is producing the recombinant polyketide in its own right, for example, a gene placed in an *E. coli* won't produce a modified polyketide, thus the cell needs to be described as producing the modifying polyketide. It is suggested that the claim is amended to read "wherein said recombinant cell is not *S. erythraea* and said recombinant cell produces a polyketide" or culturing a recombinant cell transformed with the nucleic acid of claim 1". Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 21 and the dependent claim hereto lacks clear antecedent basis for "the unmodified polyketide", note that the claim only recites "a modified polyketide" in the preamble.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 16-17, 21-22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by McDaniel et al. U.S. Patent No. 6,524,841, October 8, 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

McDaniel et al. teach recombinant nucleic acids that encode all or a portion of the megAI gene of the megalomicin polyketide synthase of *Micromonosporas megalomicea* (abstract). McDaniel et al. disclose modifying enzymes which include those enzymes involved in the conversion of 6-DEB into a megalomicin, said enzymes are encoded by megF, megK among others (paragraph [45]), see claims 1-3. Mc Daniel et al. also teach a host cell (paragraph [16]), vector (paragraph [14]) and method of making said protein (paragraph [12]), see claims 16-17 and 21-22. Note that the patent discloses a drawing (see page 1 of the patent and Fig. 9) that displays a cosmid (KOS079) having 40kb which is identical to the one shown in Figure 1 of the claimed invention. Thus, the genes for example, MegK or MegBVI, would be on this segment. The gene cluster claimed is from the same organism and cosmid as claimed. In addition, the patent displays the cosmid (KOS079-124B, having 40kb) which would have the genes for example MegF, MegBIII, or MegL on that segment (see claim 24). As the same cosmids from the same organism genome is disclosed in the patent, the genes would inherently be present. Therefore, the limitations of the claims are met by the reference.

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7. Claims 1-3, 16-17, 21-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Volchegursky et al. (Molecular Microbiology, vol. 37 (4), pages 752-762, 2000) as evidenced by McDaniel et al. U.S. Patent No. 6,524,841, October 8, 1999).

Volchegursky et al. teach the cloning and sequencing of a 48kb segment of the megalomicin (meg) biosynthetic gene cluster which contains the modular polyketide synthase (PKS) and the complete pathway for megosamine biosynthesis. Volchegursky et al. disclose enzymes such as megF (see claims 1-3, page 752 and 755 of the reference). The process used by Volchegursky et al. involves host cells, vector and said process produced the enzymes as claimed, therefore, claims 16-17 and 21-22 are anticipated (see pages 759-760). Note that the reference provides a drawing on page 754 which shows two cosmids (KOS079-138B and KOS079-124B) which would inherently possess the genes recited in for example claim 1 as evidenced by the McDaniel et al. patent (see abstract and Figure 9). As the same cosmids from the same organism genome is disclosed in the patent, the genes would inherently be present (see claim 24). Therefore, the limitations of the claims are met by the reference.

***Response to Applicant's Arguments:***

8. Applicant's arguments have been fully considered and the rejections/objections of record have been withdrawn. Note however, that new rejections have been instituted or re-instituted for the reasons set forth above and herein. With regard to the rejections under 35 U.S.C. 102, the rejections have been re-stated as they were prematurely withdrawn. Previously applicant stated that the amendment to delete MegF and MegK from the claims obviated this

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ground of rejection, however, that argument is not persuasive. Upon due reconsideration the reference was re-applied because the reference teaches the same cosmid from the same organism genome, thus would inherently possess the recited genes whether sequenced or not. Both the Volchegursky et al. and the McDaniel et al. references disclose KOS079-138B exhibited in Figure 1 of the instant application which comprises for example gene MegK and disclose another cosmid KOS079-124B which would possess genes such as MegL as evidenced by the length demonstrated in the patent (see page 1 of the McDaniel et al. patent). Therefore, the references remain relevant to the claimed invention. Also note that new grounds of rejections have been instituted under 35 U.S.C. 112, first and second paragraphs for the reasons stated above.

### ***Conclusion***

9. No claims are presently allowable. Claims 25-31 are objected to as depending from a rejected based claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS *HR*

Primary Examiner *4/13/07*

HOPE ROBINSON  
PRIMARY EXAMINER